The Rejection Under 35 U.S.C. § 112, First Paragraph Should Be Withdrawn

Claims 23-33, 35-41 and 43-57 stand rejected under 35 U.S.C. §112, first paragraph because the specification, while being enabled for the specific tumors disclosed, allegedly does not reasonably provide enablement for the term "tumors" and, thus, allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

The Examiner contends that cancer therapy remains unpredictable and that the specification lacks guidance or working examples such that one of ordinary skill could not use the entire scope of the claimed invention. Applicants respectfully disagree.

First, the claims are directed to the use of a single commercially available compound. Second, the specification provides detailed description of the dosages to be used and the cancers to be treated (*see, e.g.*, pages 20, 23 and 24 of the specification). Thus, the specification is enabling. Third, as the Examiner is well aware, under *In re Brana*, 51 F.2d 1560, 1566, 34 U.S.P.Q.2d 1437, 1441 (Fed. Cir. 1993), the specification need not provide human data to demonstrate enablement. Finally, thalidomide has been used clinically against cancer since Applicant's invention thus demonstrating the enablement of the claims. *See, e.g.*, Rajkumar, 2001, "Current status of thalidomide in the treatment of cancer", Oncology 15(7):867-874.

The Examiner has also suggested that amending the claims to recite "tumors sensitive to thalidomide" would overcome the rejection. Since the Applicant wishes to claim effective uses of thalidomide in treating cancer, Claims 23, 41 and 49 have been amended to recite "tumors sensitive to thalidomide" as suggested by the Examiner. Applicant respectfully submits that the pending claims, before and after the amendment, are fully enabled by the instant specification as originally filed, and covers the use of thalidomide against any tumor that is responsive thereto. Applicant requests withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

The Rejection Based on Nonstatutory Double Patenting Should Be Withdrawn

Claims 23-57 of the present application (Application No. 09/704,054; "the '054 application") are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 5,629,327 ('327 patent). The Examiner alleges that, although the conflicting claims are not identical, they are not patentably distinct.

Without acquiescing in the Examiner's rejection, Applicant submits herewith a Terminal Disclaimer under 37 C.F.R. § 1.321(b) by the assignee of the above-identified application (1) disclaiming any part of any patent granted on the '054 application which could extend beyond the expiration date of the '327 patent; and (2) ensuring that any such patent granted on the '054 application shall be enforceable only for and during such period that such patent is commonly owned with the '327 patent[1].

By this terminal disclaimer, and as stated therein, the assignee does not disclaim any terminal part of any patent granted on the '054 application prior to the expiration date of the full statutory term of the '327 patent, as presently shortened by any terminal disclaimer, in the event that the '327 patent later expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. § 1.321, has all claims canceled by a reexamination certificate, or is otherwise terminated prior to the expiration of its statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above. Applicant submits that the submission of the Terminal Disclaimer obviates the rejection based on nonstatutory double patenting, and respectfully requests its withdrawal.

CONCLUSION

Entry of the foregoing amendments and remarks into the file history of the above-identified application is respectfully requested. Applicant believes that the foregoing amendments and remarks place the claims in condition for allowance. Withdrawal of all

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[1] Since this application was filed on November 11, 2000, it falls under the statute that sets its term as twenty years from its earliest application date.

EXHIBIT A

Marked up version of amended claims
Application No. 09/704,054

23. (amended) A method for inhibiting [tumor] the formation or growth of tumors sensitive to thalidomide [by inhibiting angiogenesis] in a human or animal comprising administering to said human or animal an [angiogenesis inhibiting] effective amount of thalidomide or a pharmaceutical composition comprising thalidomide.

41. (amended) A method for inhibiting metastasis of tumors sensitive to thalidomide in a human or animal having at least one primary tumor comprising administering to said human or animal an [angiogenesis inhibiting] effective amount of thalidomide [to said human or animal] or a pharmaceutical composition comprising thalidomide.

49. (amended) A method for reducing the recurrence of a tumor sensitive to thalidomide [by inhibiting angiogenesis] in a human or animal comprising administering to said human or animal an [angiogenesis inhibiting] effective amount of thalidomide [to said human or animal] or a pharmaceutical composition comprising thalidomide.

EXHIBIT B

Claims that will be pending in Application No. 09/704,054
as of entry of the instant amendment

23. (amended) A method for inhibiting the formation or growth of tumors sensitive to thalidomide in a human or animal in need thereof comprising administering to said human or animal an effective amount of thalidomide.

24. The method of Claim 23 wherein the tumor formation or growth is in a mammal.

25. The method of Claim 24 wherein the thalidomide is administered orally, sublingually, buccally, rectally, vaginally, transdermally, topically, basally, or parenterally.

26. The method of Claim 23 wherein the thalidomide is administered in the form of a tablet or capsule.

27. The method of Claim 23 wherein the thalidomide is administered in an amount between approximately 0.1 and approximately 300 mg/kg/day.

28. The method of Claim 24 wherein the thalidomide is administered in an amount between approximately 0.5 and 50 mg/kg/day.

29. The method of Claim 28 wherein the thalidomide is administered in an amount between approximately 1 and approximately 10 mg/kg/day.

30. The method of Claim 24 wherein the mammal is at risk for developing a tumor.

31. The method of Claim 23 wherein the thalidomide is administered in the form of a lozenge, a cachet, a solution, a suspension, an emulsion, a powder, an aerosol, a spray, a suppository, a tampon, a pessary, a pastille, an ointment, a cream, a paste, a foam or a gel.

32. The method of Claim 24 wherein the mammal is a human.

33. The method of Claim 23 wherein the human has a primary tumor.

34. The method of Claim 33 wherein the primary tumor is selected from the group consisting of Kaposi's sarcoma, hemangiomas, solid tumors, blood-born tumors, rhabdomyosarcoma, retinoblastoma, Ewings's sarcoma, neuroblastoma, osteosarcoma, leukemia, neurofibroma, pyogenic granulosum, and breast cancer.

35. The method of Claim 33 wherein the thalidomide is administered orally, sublingually, buccally, rectally, vaginally, transdermally, topically, basally, or parenterally.

36. The method of Claim 33 wherein the thalidomide is administered in an amount between approximately 0.1 and approximately 300 mg/kg/day.

37. The method of Claim 36 wherein the thalidomide is administered in an amount between approximately 0.5 and approximately 50 mg/kg/day.

38. The method of Claim 37 wherein the thalidomide is administered in an amount between approximately 1 and approximately 10 mg/kg/day.

39. The method of Claim 33 wherein the thalidomide is administered in the form of a tablet or capsule.

40. The method of Claim 33 wherein the thalidomide is administered in the form of a lozenge, a cachet, a solution, a suspension, an emulsion, a powder, an aerosol, a spray, a suppository, a tampon, a pessary, a pastille, an ointment, a cream, a paste, a foam or a gel.

41. (amended) A method for inhibiting metastasis of tumors sensitive to thalidomide in a human or animal having at least one primary tumor comprising administering to said human or animal an effective amount of thalidomide.

42. The method of Claim 41 wherein the primary tumor is selected from the group consisting of Kaposi's sarcoma, hemangiomas, solid tumors, blood borne tumors, rhabdomyosarcoma, retinoblastoma, Ewings's sarcoma, neuroblastoma, osteosarcoma, leukemia, neurofibroma, pyogenic granulosum, and breast cancer.

43. The method of Claim 41 wherein the thalidomide is administered orally, sublingually, buccally, rectally, vaginally, transdermally, topically, basally, or parenterally.

44. The method of Claim 41 wherein the thalidomide is administered in an amount between approximately 0.1 and approximately 300 mg/kg/day.

45. The method of Claim 44 wherein the thalidomide is administered in an amount between approximately 0.5 and approximately 50 mg/kg/day.

46. The method of Claim 45 wherein the thalidomide is administered in an amount between approximately 1 and approximately 10 mg/kg/day.

47. The method of Claim 41 wherein the thalidomide is administered in the form of a tablet or capsule.

48. The method of Claim 41 wherein the thalidomide is administered in the form of a lozenge, a cachet, a solution, a suspension, an emulsion, a powder, an aerosol, a spray, a suppository, a tampon, a pessary, a pastille, an ointment, a cream, a paste, a foam or a gel.

49. (amended) A method for reducing the recurrence of a tumor sensitive to thalidomide in a human or animal comprising administering to said human or animal an effective amount of thalidomide.

50. The method of Claim 49 wherein the human or animal is undergoing cancer therapy.

51. The method of Claim 49 wherein the tumor is no longer present in said human or animal.

52. The method of Claim 49 wherein the thalidomide is administered orally, sublingually, buccally, rectally, vaginally, transdermally, topically, basally, or parenterally.

53. The method of Claim 49 wherein the thalidomide is administered in an amount between approximately 0.1 and approximately 300 mg/kg/day.

54. The method of Claim 53 wherein the thalidomide is administered in an amount between approximately 0.5 and approximately 50 mg/kg/day.

55. The method of Claim 54 wherein the thalidomide is administered in an amount between approximately 1 and approximately 10 mg/kg/day.

56. The method of Claim 49 wherein the thalidomide is administered in the form of a tablet or capsule.

57. The method of Claim 49 wherein the thalidomide is administered in the form of a lozenge, a cachet, a solution, a suspension, an emulsion, a powder, an aerosol, a spray, a suppository, a tampon, a pessary, a pastille, an ointment, a cream, a paste, a foam or a gel.

58. The method of Claim 23 wherein said tumor is a solid or blood borne tumor.